



August 27, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket No. 02N-0276; Comments on Section 305 (Registration) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 in response to July 17, 2002 letter to the FDA Foods Community from CFSAN Director Joseph Levitt.

Dear Sir/Madam,

NNFA is the oldest and largest, non-profit trade association dedicated to protecting and advancing the natural products industry. Our members include retailers, manufacturers and distributors of health food products, dietary supplements, and natural cosmetics. We submit the following recommendations regarding section 305 (Registration) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) so that they can be taken under consideration by the Agency as it develops proposed regulations.

I. Retail food establishments are exempt from registration under the Act.

Only "facilities" are required to register with the Secretary under Section 305 of the Act. The term "facility," for purposes of this Act's registration requirement does not include "retail food establishments."

Sec. 415(b) FACILITY- For purposes of this section:

(1) The term 'facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).

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The U.S. House of Representative Conference Report and debate on the Act makes clear that Congress intended retail food establishments, including facilities attendant to their operations, to be exempt from registration under this Act:

The bill would authorize the Secretary to broadly impose the registration requirement to domestic facilities engaged in processing or distributing food for human consumption as the Secretary deems necessary. However, the registration requirement would not authorize registration of farming facilities (including facilities attendant to harvesting of food crops), restaurants or other retail food establishments (including facilities attendant to their operations, which are under the same ownership or management) or most fishing vessels. (148 CongRec. H2844-01)

II. The plain meaning of the term "other retail establishments" as used in Section 415(b) of the Act should be understood to include health food stores

The plain and ordinary meaning of the phrase "other retail food establishments," as used in Sec. 415(b), includes health food stores, among other retail grocers. Health food stores can range from shops that sell only dietary supplements to those which offer a produce, dairy and meat selection, among other retail food items.

Furthermore, to interpret this term otherwise would subject a group of companies to registration that Congress never intended to have FDA register. The House Conference Report and debate on Sec. 415 of the Act makes this clear:

The Managers intend that, for purposes of this section, the term "retail food establishments" includes establishments that store, prepare, package, serve or otherwise provide articles of food directly to the retail consumer for human consumption, such as grocery stores, convenience stores, cafeterias, lunch rooms, food stands, saloons, taverns, bars, lounges, catering or vending facilities, or other similar establishments that provide food directly to a retail consumer. The term does not include a warehouse that does not provide articles of food directly to a retail consumer as its primary function. (148 CongRec. H2685-02)

III. Health food stores should be exempt from registration under the Act regardless of whether they manufacture, process, pack or hold food, if providing articles of food to a retail consumer is their primary function.

There may be some confusion with regard to the exemption for "retail food establishments" as to retailers, like health food stores, that process, pack or hold food. Some examples of how health food stores may process, pack or hold foods for the consumer include when they: unpack and display produce, offer for sale foods like nuts or dried fruits that are received in bulk and repackaged, or operate a juice-bar. We would

like for the Agency to provide clear guidance and examples in order to clarify this exemption.

It is our position that retail food establishments that conduct processing or other intermediate activities, in order to provide articles of food directly to a retail consumer, are not subject to registration. Simply put, there is no exemption from the exemption in Section 415(b). Only "facilities" are required to register, the term "facility" does not include "retail food establishments," and whether a retailer processes, packs or holds an item for sale directly to the consumer should not override the exemption.

Furthermore, Congress clearly did not intend for retail food preparation, or processing, to be a trigger for the registration requirement. In fact, restaurants are also exempt. For these reasons, we believe that retail food establishments, even those that process, pack or hold food for direct sale to consumers, do not fall under the Acts registration requirement.

In conclusion, implementation of this Act presents a daunting, but very worthwhile, task and NNFA will make every effort to convey the requirements under it to the natural products industry at large. NNFA will submit comments on FDA's proposed rules and we look forward to working with the Agency to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David Seckman", with a stylized, flowing script.

David Seckman
Executive Director and CEO